

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Office**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/588,637 01/19/96 BARBOUR

A 454312-2420

020999  
FROMMER LAWRENCE & HAUG  
745 FIFTH AVENUE- 10TH FL.  
NEW YORK NY 10151

HM12/1108

**EXAMINER**

SWARTZ, R

ART UNIT	PAPER NUMBER
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1645

**DATE MAILED:**

11/08/01

*24*

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

<b>Advisory Action</b>	Application No. <b>08/588,637</b>	Applicant(s) <b>Barbour et al</b>
	Examiner <b>Rodney P. Swartz, Ph.D.</b>	Art Unit <b>1645</b>

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

THE REPLY FILED 20August2001 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

a)  The period for reply expires 3 months from the mailing date of the final rejection.

b)  In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for the reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.  A Notice of Appeal was filed on 20August2001. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.  The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.

3.  The proposed amendment(s) will not be entered because:

(a)  they raise new issues that would require further consideration and/or search. (See NOTE below);

(b)  they raise the issue of new matter. (See NOTE below);

(c)  they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d)  they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

4.  Applicant's reply has overcome the following rejection(s):  
\_\_\_\_\_

5.  Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claim(s).

6.  The a)  affidavit, b)  exhibit, or c)  request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
see attached Detailed Action

7.  The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

8.  For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):  
Claim(s) allowed: none  
Claim(s) objected to: none  
Claim(s) rejected: 1-4, 6-10, 12, and 13

9.  The proposed drawing correction filed on \_\_\_\_\_ a)  has b)  has not been approved by the Examiner.

10.  Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.

11.  Other:

Art Unit: 1645

### **DETAILED ACTION**

1. Applicants' Response to Final Office Action, received 20August2001, paper#22, is acknowledged.
2. Claims 1-4, 6-10, 12, and 13 are pending and currently under consideration.

#### **Rejection Maintained**

3. The rejection of claims 1-4, 6-10, 12, and 13 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 2 of U.S. Patent No. 5,688,512, in view of Bergstrom et al (U.S. Pat. No. 5,523,089) or Cohen (*Immunization*, in, *Basic & Clinical Immunology*, 3rd ed., Fudenberg HH, Stites DP, Caldwell JL, Wells JV, eds., 1980) is maintained.

Applicants argue that the subject matter of the claims of U.S. Pat. No. 5,688,512 would not have been obvious from the subject matter of the instant claims, and *vice versa*, and that the rejection is based upon hindsight by the examiner. There is nothing in the disclosure of claim 2 that teaches or suggest the particular mucosal administration of the composition to produce the generalized response of the instant claims.

The examiner has considered applicants' arguments, but does not find them persuasive for reasons of record put forth in the original rejection.

For example, in U.S. Pat. No. 5,688,512:

Claim 2. A method of inducing a protective immunological response against *Borrelia burgdorferi* in an animal or human susceptible to Lyme disease comprising

Art Unit: 1645

administering the vaccine of claim 1 to the animal or human in an amount effective for inducing the protective immunological response.

Claim 1. A vaccine comprising: substantially pure OspA, and an immunologically acceptable carrier or vehicle.

Thus, claim 2, when combined with claim 1 from which it depends, reads:

A method of inducing a protective immunological response against *Borrelia burgdorferi* in an animal or human susceptible to Lyme disease comprising administering a vaccine comprising substantially pure OspA, and an immunologically acceptable carrier or vehicle to the animal or human in an amount effective for inducing the protective immunological response.

Claim 1 of the Instant application reads:

A method for inducing an immunological response in a mammalian host susceptible to Lyme disease or *Borrelia burgdorferi* infection comprising mucosally administering a composition comprising substantially pure outer surface protein A (OspA) and a carrier or diluent.

Art Unit: 1645

Therefore, the scope of the recitation in claim 2 of U.S. Pat. No. 5,688,512 of "comprising administering a vaccine" encompasses any administration (mucosal, intramuscular, subcutaneous, etc), i.e., the administration of instant claim 1 is an obvious variant.

### **Conclusion**

4. Claims 1-4, 6-10, 12, and 13 remain rejected.
5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-0196.



RODNEY P SWARTZ, PH.D  
PRIMARY EXAMINER  
Art Unit 1645

November 8, 2001